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Notice of Allowability

Application No.

09/976,804

Examiner

Sandra Saucier

Applicant(s)

POLYAK ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments arguments and declaration filed 5/13/05.
2. ☒ The allowed claim(s) is/are 8-12 and 20-27.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

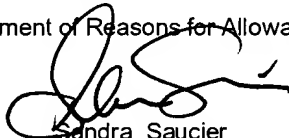
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Sandra Saucier
Primary Examiner
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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with B. Higgins on 8/23/05. The application has been amended as follows:

IN THE CLAIMS

Claims 1, 6, 7, 13-19 have been canceled.

In claim 8, "claim 1" has been replaced by ---claims 9, 10 or 11---.

Claims 9-12 and 19 now read:

9. An organ or biological tissue preservation aqueous cold storage solution comprising:

about 1,000 micrograms/L prostaglandin E1,

about 10 mg/L nitroglycerin,

about 0.2 mg/L N-acetylcysteine,

about 50-150 mM potassium lactobionate,

about 10-40 mM KH_2PO_4 ,

about 2-8 mM MgSO_4 ,

about 10–50 mM raffinose,
about 1–20 mM adenosine,
about 1–10 mM allopurinol, and
about 40–60 g/L pentastarch.

10. An organ or biological tissue preservation aqueous cold storage solution comprising:

about 1,000 micrograms/L prostaglandin E1,
about 10 mg/L nitroglycerin,
about 0.2 mg/L N-acetylcysteine,
about 75–125 mM potassium lactobionate,
about 20–30 mM KH_2PO_4 ,
about 3–7 mM MgSO_4 ,
about 20–40 mM raffinose,
about 2–10 mM adenosine,
about 1–5 mM allopurinol, and
about 45–55 g/L pentastarch.

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11. An organ or biological tissue preservation aqueous cold storage solution comprising:

about 1,000 micrograms/L prostaglandin E1,

about 10 mg/L nitroglycerin,

about 0.2 mg/L N-acetylcysteine,

about 100 mM potassium lactobionate,

about 25 mM KH_2PO_4 ,

about 5 mM MgSO_4 ,

about 30 mM raffinose,

about 5 mM adenosine,

about 1 mM allopurinol, and

about 50 g/L pentastarch.

12. The cold storage solution of claim 9, 10 or 11 further comprising sterile water.

19. The cold storage solution of claim 12, further comprising about 700–900 mls sterile water.

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Claim 20, line 2, "a cold storage solution comprising a prostaglandin with a vasodilatory membrane stabilizing, platelet aggregation prevention upon reperfusion , and complement activation inhibitory properties, a nitric oxide donor and glutathione-forming agent" has been replaced by

---the cold storage solution of claim 9, 10 or 11---

Claim 25 now reads:

25. A method of preparing the organ or biological tissue preservation

solution of claim 9, 10 or 11 comprising:

providing a solution with sterile water;

adding the potassium lactobionate, the potassium phosphate, the

raffinose, the adenosine, the allopurinol and the pentastarch to the

solution; and

mixing the prostaglandin E1, the nitroglycerin and the N-acetylcysteine into the

solution.

REJOINDER OF CLAIMS

Claims 8-12 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 20-27, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 20-27 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

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Claims 13-19, not directed to the process of making or using the patentable product, will not be rejoined.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicant has presented evidence of unexpected results when about 1,000 micrograms/L prostaglandin E1, about 10 mg/ml nitroglycerin and about 0.2 mg/L of N-acetylcysteine is added to Viaspan® and used in the preservation of kidney.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier
Primary Examiner
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